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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,293	08/06/2001	Timothy W. Conner	16517.254	7785

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EXAMINER	
CLOW, LORI A	
ART UNIT	**PAPER NUMBER**
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/922,293	CONNER ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,14-18,21,23 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10, 14-18, 21, 23, and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 4 January 2007, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 10, 14-18, 21, 23, and 24 are currently pending. Claims 1-9, 11-13, 19, 20, and 22 have been cancelled.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21, as amended, recites "a recombinant nucleic acid construct comprising the isolated transcription factor of claim 10". The claim is unclear because it is not possible for the recombinant nucleic acid construct to comprise an isolated transcription factor. Rather, the construct should comprise the nucleic acid encoding the transcription factor. Clarification is requested.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 24, as amended, recites "a plant genome comprising the substantially purified nucleic acid molecule of claim 23. The specification fails to provide a description of a genus that represents all plant genomes, and therefore the claim lacks written description. Further, the specification does not provide support for the breadth of the recombinant molecule now recited. The specification describes transformed plants comprising nucleic acids with specific parts (A), (B), and (C) at pages 39-41 and in original claim 6. However, there is no support for a plant genome which comprises a recombinant molecule without the portions and therefore, claim 24 lacks written description in the specification as originally filed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 14-18, 21, 23, and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must know a priori that SEQ ID NO: 1 has transcription factor activity. For the reasons set forth below, this constitutes undue experimentation.

b) and c) The specification provides examples for a general description of homeobox transcription factors (page 31). The specification states generally that the present invention provides a substantially purified maize, soybean, or *Arabidopsis thaliana* transcription factor or fragment thereof selected from the group consisting of SEQ ID NOS: 1-3853 and that these are members of the homeobox transcription factor family (page 32). However, the specification provides no disclosure that is specific to SEQ ID NO: 1 as having transcription factor activity, such that one of skill in the art would know how to make the instant invention. Rather, the specification discloses that SEQ ID NO:1 in Table A is homologous to GenBank accession number g642128, stating that there is 100% identity. However, an alignment (provided as an attachment to the Office Action herein), shows that SEQ ID NO:1 is only 83.4% identical to

Genebank Accession Number g642128. Further, the alignment shows that the query sequence contains a MADS box at nucleotide position 24-194, matching nucleotides 77-247 of SEQ ID NO:1. However, the specification is not specific for SEQ ID NO:1 per se to act as a transcription factor, as no activity specific to SEQ ID NO:1 is evident. In addition, the K box, an important homeobox transcription factor domain is absent in SEQ ID NO:1 Therefore, without such active domains, one of skill in the art would not know how SEQ ID NO: 1 functions as a transcription factor without undue experimentation.

d) The invention is drawn to an isolated transcription factor. However, the specification is not enabling for transcription factor of SEQ ID NO: 1, as discussed above.

e) It would have been well known in the art that single or multiple substitutions or deletions can alter biomolecular function in many instances, albeit not all. In the absence of any factual evidence that characterizes the specific **structural and functional** components of a biomolecule, the effects of these changes are largely unpredictable. In some cases mutations will lend no effect, as in silent mutations and in others, up regulation or down regulation may occur. There have been several publications documenting the unpredictability of the relationship between sequence, structure and function, even though it has been found in some cases that conserved biomolecules have related functions after significant physical research. Such research, however, is lacking in the current specification.

The prediction of gene function and protein activity based on alignments is highly unpredictable. Even the term "gene function" has a variety of definitions that only make sense in context. Bork et al. (Bork et al. (1998) JMB 283 :707-725: PTO-1449) discuss the many differing definitions that "gene function" or "protein function" can have. Enzymatic activity,

activity within a pathway, and potential activity with or on a partner protein, such as in receptor activity, are possible definitions, and Bork et al. note that these activities are only being predicted qualitatively, and not necessarily accurately. Other definitions which Bork et al. note can be predicted with even less certainty include expression patterns, **regulation** (functional link), kinetic properties, localization and concentration effects. Bork et al. state that most functional features of the respective proteins will remain hidden, despite attempts at prediction of those features. Furthermore, this information transfer from well studied proteins to uncharacterized genes has to be done carefully since (i) similar protein structures or functions (in particular in important details such as recognition loops (as in receptor domain loops) and (ii) the annotation of the database protein might be incomplete or even wrong (page 708).

f) The skill of those in the art of molecular biology is high.

g) The prior art indicates that "[p]rediction of function from sequence is a considerably more complex enterprise than a simple sequence database search which represented the entire repertoire or tools a few years ago." (Bork et al., page 721) This indicates that more than a simple alignment between one or more protein sequences at one or more residues is required to even suggest said proteins may be have similar function because of conserved sites. It is noted that SEQ ID NO: 1 is assumed to have transcription factor activity based on a region with identity to a known MADS box in a protein known to be a transcription factor. However, SEQ ID NO: 1 is not limited to comprise the MADS box region, nor to comprise any other known conserved domain necessary for transcription factor activity.

h) The claims are drawn to SEQ ID NO:1. The skilled practitioner would first turn to the instant specification for guidance. However, the instant specification does not provide specific

guidance to make and/or use SEQ ID NO: 1, as it is not disclosed specifically whether SEQ ID NO:1 has transcription factor activity. As such, the skilled practitioner would turn to the prior art for such guidance, however, the prior art shows that alterations in sequence (i.e. not 100% identity to a know TF) are not predictable. Finally, said practitioner would turn to trial and error experimentation to determine whether said altered sequences (i.e. sequences that are not 100% identical) are indeed similar or have similar activity through the methods discussed by Bork et al, including substantial bench research. Such represents undue experimentation.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also

enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

March 18, 2007
Lori A. Clow, Ph.D.
Art Unit 1631

Lori A Clow
Patent Examiner
3/18/07